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DETAILED DESCRIPTION

[Detailed Description of the Invention]**[0001]**

[Industrial Application] The skin protective layer constituent used for the tapes which this invention fixes to the skin the skin protective layer constituent of medical application, especially for a long period of time, It is related with the skin protective layer constituent used for immobilization of the part which infection by the onset of dermatitis and bacilli, such as management of the place which is easy to be polluted, for example, an artificial anus, an artificial urinary bladder, and various fistulas and the anus, an operative wound, and a trauma, tends to carry out, and protection.

[0002]

[Description of the Prior Art] A skin protective layer means the covering material which has a skin protective action (maintenance operation of a physiological state of the skin). That is, the protective layer which has pH maintenance or the buffer action which keeps constant pH of the water absorption action which absorbs the fungistatic action, the sweat, and the leaching solution for prevention of infection, and is held to moderate humidity, and the skin is said. In the product, that to which an adhesion operation, a cushion operation, etc. other than the above-mentioned function were added exists.

[0003] An artificial anus, an artificial urinary bladder, various fistula articles, and a wound administrative article are one of those which are commercialized comparatively mostly in these. For example, in order to combine with the skin around an elimination hole the pouch for storing the facilities, urine, and body fluid which are excreted from an elimination hole in the case of an artificial anus, an artificial urinary bladder, and various fistula articles, the skin protective layer is used, but. The skin protective layer for this combination is used in order to prevent the dermatitis under the influence of skin inhibitor and pH which are included in an excretion ingredient. In the case of a wound administrative article, ** is covered thoroughly,

permeation of the bacillus from the outside is prevented, it sticks to a wound part moderately and infection pain prevention is aimed at, in order to give moderate moisture, a superfluous leaching solution is absorbed, moreover it does not adhere to a wound surface, but in order do not give a scar and to treat it, a skin protective layer is used.

[0004]What uses hydrophilic polymer alone as a constituent which constitutes such a skin protective layer, What consists of hydrophilic polymer and polyhydric alcohol for processing it into paste state and gel, hydrophilic polymer, and a hydrophobic polymer are used as the main base, and there are granularity which blended modifiers, such as a tackifier, a thickener, a moisturizer, a shape retaining agent, and a dispersing agent, paste state, a thing of gel and a sheet shaped, etc. In these constituents, as one of the hydrophilic things, pH of a constituent is made into the acidity of 2-4, and there are some which used pectin as what controls propagation of a bacillus. In order to absorb moisture like sweat and to give humid adhesive strength at JP,54-38475,A into the adhesives compound for ostomies for equipping with an ostomy appliance implement the body surface around puncturing formed in the patient by artificial ostomy operation, Making pectin contain as one of the hydrocolloid rubbers is indicated. In the medical-application bonding agent which becomes JP,54-4491,A from the homogeneous mixture containing the mixture of pressure-sensitive adhesion components, mineral oil and hydrocolloid rubber, an adhesive strength enhancement agent, or hydrocolloid rubber and an adhesive strength enhancement agent, A patient's pain is made to keep it calm and it is indicated that it is advantageous to use pectin as one of the hydrocolloid rubbers in order to ease a pain. In the pressure-sensitive adhesion dressings which becomes JP,1-99564,A from the pressure-sensitive adhesive layer containing an elasticity support material and a pharmacological active ingredient, The adhesiveness (humid adhesiveness) to the body surface damp to the pressure sensitive adhesive composition is given, and using pectin as suitable water soluble matter in order for a pharmacological ingredient to reform the mechanism emitted from dressings is indicated. In the skin protective layer which becomes JP,57-169414,A from an adhesive rubber Mr. bonding agent ingredient, hydrocolloid, and a flow nature improving agent, Karaya gum is indicated as one ingredient of hydrocolloid, and this karaya gum is close to pH of human being's skin at pH 4.5 to 4.7 acescence, And acting as alkali to strong acid, and having the buffer capacity committed as acid to an alkaline substance, and giving absorptivity, antibacterial properties, and elasticity is indicated.

[0005]However, in the conventional skin protective layer, there is nothing corresponding enough to the bacillus which is one of the important elements of a skin protective layer, and fungistatic action has a still bigger problem.

[0006]

[Problem(s) to be Solved by the Invention]The purpose of this invention is to provide the high constituent of the fungistatic action which is an element important as a skin protective layer.

[0007]

[Means for Solving the Problem]In order to attain the above-mentioned purpose, in this invention, an effective dose of apple origin pectin for giving a hydrophilic component and sterilization nature into a pressure-sensitive binder ingredient is contained.

[0008]As a pressure-sensitive binder ingredient, nature and a composite elastomer component, for example, crude rubber, Anything of a medical-application compound which uses polyisobutylene, polyisoprene, SIS, polyurethane, polyacrylic ester, polyvinyl butyl ether, a polysiloxane, etc. as the main base, and is adhesive can be used.

[0009]As a hydrophilic component, any of nature, a semisynthesis, and composition may be sufficient, for example, as a natural hydrophilic component Karaya gum, Cyamoposis Gum, TORAKANTO gum, locust bean gum, starch, sodium alginate, natural water solubility polymers, such as pectin, gelatin, and collagen, and a cellulose type (CMC.) There are some which compounded hydrophilic polymer of semisyntheses, such as EC, HEC, a starch system (soluble starch, CMS, JIARUDEBIDO starch), PVP, sodium polyacrylate, and polyethylene oxide, and composition, acrylic acid, synthetic polymer, such as starch, and natural polymer.

[0010]As pectin, in a commercial base Citruses origin pectin (what is obtained from pericarp of lemon, a lime, an orange, and a grapefruit), Apple origin pectin (what is obtained from pericarp of an apple) is known, and the typical application is for gel organization potency, and the most is used by a food field, and is used as a shape retaining agent by drugs or a cosmetic field a little. Apple origin pectin is used and methoxy[low]-izing or methoxy[high]-izing of the esterification degree is [in / especially / this invention] also good. Content of apple origin pectin is 5 to 60%, and is 10 to 30% preferably. This is because fungistatic action is insufficient if less than 5%, will become hard with acidity of pectin, and secondary elaboration will become difficult or other operations, for example, adhesiveness, pliability, adhesion, etc. will become insufficient, if 60% is exceeded.

[0011]

[Function]In this invention, the function which produces fungistatic action with sufficient apple origin pectin contained in a pressure-sensitive binder ingredient, and is demanded as other skin protective layers with a pressure-sensitive binder ingredient and a hydrophilic component is produced.

[0012]

[Example]Next, this invention is further explained about an example.

[0013]First, the validity of the fungistatic action of the apple origin pectin used by this invention is explained as compared with it of citruses origin pectin. As apple origin pectin, NL grade of the formation of methoxy [high] by the help SHUTO light company in Germany, 62 to 66% of an esterification degree, and pH 2.8**0.2, Using OM grade of the formation of methoxy [low], 38 to 40% of an esterification degree, and two kinds of pH 2.8**0.2, as citruses origin pectin for

comparison, The DD-Slowset grade of the formation of methoxy [high] made from GENYU, 63 to 67% of an esterification degree, and pH 3.6-4.4, Using LM-102 grade of the formation of methoxy [low], 32% of an esterification degree, and two kinds of pH 4.0-5.0, the dose of a radappertization method is changed as the concentration of pectin, and sterilization, and the result of having made various kinds of bacilli acting and having investigated the sterilization effect is shown in Tables 1-5.

[0014]

[Table 1]

黄色ブドウ球菌

添加菌数 = $8.27 \times 10^4 / ml$

γ -radiation サンプル種類	%	pectin			
		APPLE PECTIN(ヘルプショトライ特社)		CITRUS PECTIN (ゲニュー社)	
		N L (HM)	O M (LM)	DD-Slowset (HM)	LM-102 (LM)
0M	1%	1.72×10^4	0	0	1.91×10^4
	3%	0	0	0	1.40×10^4
	5%	0	0	0	6.36×10^3
1M	1%	1.91×10^4	0	1.91×10^4	1.53×10^4
	3%	0	0	0	1.14×10^4
	5%	0	0	0	9.03×10^3
2.5M	1%	1.91×10^4	0	2.03×10^4	8.27×10^4
	3%	0	0	0	6.36×10^4
	5%	0	0	0	6.36×10^4

[0015]

[Table 2]

連鎖球菌

添加菌数 = $4.59 \times 10^3 / \text{ml}$

サンプル種類 γ -radiation		pectin			
		APPLE PECTIN(ヘルナシュトライ社)		CITRUS PECTIN(ケニヤ社)	
γ -radiation %	N L (H M)	O M (L M)	DD-Slowset(HM)	LM-102 (LM)	
	1%	0	0	1.09×10^3	2.31×10^3
0 M	3%	0	0	9.82×10^3	1.31×10^3
	5%	0	0	9.00×10^3	1.29×10^3
	1%	0	0	2.31×10^3	3.34×10^3
1 M	3%	0	0	2.27×10^3	3.12×10^3
	5%	0	0	2.91×10^3	3.09×10^3
	1%	0	0	3.60×10^3	4.02×10^3
2.5 M	3%	0	0	3.45×10^3	4.01×10^3
	5%	0	0	3.00×10^3	4.00×10^3

[0016]

[Table 3]

緑 膽 菌

添加菌数 = $8.90 \times 10^4 / ml$

サンプル種類 γ -radiation		pectin			
		APPLE PECTIN(ヘルプショトライ特社)		CITRUS PECTIN(ゲニュー社)	
%		N L (HM)	O M (LM)	DD-Slowset (HM)	LM-102(LM)
0 M	1%	1.78×10^3	0	6.61×10^3	5.47×10^3
	3%	0	0	0	0
	5%	0	0	0	0
1 M	1%	5.85×10^3	3.76×10^3	4.07×10^3	8.27×10^3
	3%	0	0	0	0
	5%	0	0	0	0
2.5 M	1%	1.28×10^4	7.88×10^3	8.14×10^3	1.04×10^4
	3%	0	0	0	9.16×10^3
	5%	0	0	0	0

[0017]

[Table 4]

大腸菌

添加菌数=1.07×10⁴/ml

サンプル種類 r-radiation %	pectin			
	APPLIE PECTIN(ヘルプシュトイド社)		CITRUS PECTIN (グリコ社)	
	NL (HM)	OM (LM)	DD-Slowset(HM)	LM-102(LM)
0 M	1% 2.29 ×10 ³	5.60 ×10 ³	3.18 ×10 ³	5.34×10 ³
	3% 0	0	1.27 ×10 ³	3.18×10 ³
	5% 0	0	0	8.90×10 ²
1 M	1% 4.71 ×10 ³	5.47 ×10 ³	5.60 ×10 ⁴	5.84×10 ³
	3% 0	0	3.18 ×10 ³	4.32×10 ³
	5% 0	0	0	1.65×10 ³
2.5M	1% 4.96 ×10 ³	4.58 ×10 ³	6.49 ×10 ³	5.21×10 ³
	3% 0	0	2.16 ×10 ³	2.67×10 ³
	5% 0	0	0	2.42×10 ³

[0018]

[Table 5]

カンジダ菌

添加菌数 = $2.54 \times 10^4 / ml$

サンプル種類 γ -radiation		pectin			
		APPLE PECTIN(ヘルプショット社)		CITOUS PECTIN (ゲニ-社)	
γ -radiation %	N L (H M)	O M (L M)	DD-Slowset(HM)	LM-102(LM)	
	1%	0	7.63×10^3	1.27×10^3	2.54×10^3
0 M	3%	0	0	1.27×10^3	2.42×10^3
	5%	0	0	1.02×10^3	0
	1%	1.42×10^3	1.40×10^3	1.44×10^3	1.46×10^3
1 M	3%	0	0	3.56×10^3	1.44×10^3
	5%	0	0	3.31×10^3	0
	1%	1.02×10^3	1.03×10^3	2.30×10^4	1.20×10^3
2.5 M	3%	0	0	2.16×10^4	9.09×10^3
	5%	0	0	1.55×10^4	0

[0019] To the *Staphylococcus aureus* of Table 1, detection of a bacillus did not have HM type of HM of apple origin pectin, LM, and citruses origin pectin by not less than 3% of concentration. However, even if LM type of citruses origin pectin raised concentration to 3%, the sterilization effect was hardly seen. There was no change in the fungistatic action by the dose of radappertization.

[0020] Citruses origin pectin did not have the sterilization effect in HM and LM type to the apple origin pectin HM and LM type showing fungistatic action to all to the chain ball of Table 2 1% or more. 2.5 megarads or a beam thing was also changeless in a dose as radappertization, and it was only a difference by the kind of pectin.

[0021] Although there is no sterilization effect in HM of HM of apple origin pectin, LM type, and citruses origin pectin, and LM type and both pectin showed fungistatic action to them at not less than 3% with 1% concentration to *Pseudomonas aeruginosa* of Table 3, Some which made the dose of radiation 2.5 megarads by LM type of citruses origin pectin had a phenomenon in which the sterilization effect fell.

[0022] Although HM of apple origin pectin and LM type do not have the sterilization effect and the effect came out of them from 3% by 1% concentration to the *Escherichia coli* of Table 4, by HM type, the sterilization effect came out of citruses origin pectin for the first time at 5%, and LM type did not show sterilization nature at least 5%. Influence on a dose of radiation was not

seen.

[0023]Although HM of apple origin pectin and LM type did not show the sterilization effect at 1% to the Candida bacillus of Table 5, not less than 3% showed fungistatic action. On the other hand, at least 5%, HM type is ineffective and, as for the case of citruses origin system pectin, showed fungistatic action gradually at 5% by LM type. To the amount of radappertization, it was uninfluential.

[0024]The difference was in the sterilization effect a little according to the kind of bacillus so that it might see above in Tables 1-5, but it became clear by making apple origin pectin more than 5% concentration contain that fungistatic action was shown to the bacillus of most which causes dermatitis. On the other hand, from citruses origin pectin, there is not no fungistatic action to Staphylococcus aureus, streptococci, Escherichia coli, and the Candida bacillus, or since it is weak, it is not suitable for using for a skin protective layer. Since citruses origin pectin serves as a culture medium to true fungi, its still more important thing is not preferred. Although apple origin pectin was blackish-brown-ized a little by performing radappertization as compared with citruses origin pectin, change was not produced in fungistatic action.

[0025]Next, each ingredient of the example and comparative example of this invention is shown in Table 6. What changed various combination about that for which the example used apple origin pectin, and a comparative example make combination of ingredients other than pectin the same as that of an example using citruses pectin. if the preparation method is explained about Example 1 -- polyisobutylene (Thet Lux 4T made from Nippon Oil Chemical industry.) the thing of the viscosity average molecular weight 40000, and the thing of 5T and the viscosity average molecular weight 50000 -- the ratio of 5:5 -- containing -- 43.4%, Isobutylene isoprene rubber (product ESSO Butylmade from exon-268) is taken 2.6%, Carry out application-of-pressure mixing until it becomes uniform by a pressurization mold kneader, and after that apple origin pectin (the LM type OM esterification degrees 38-40 by a help SHUTO light company, pH 2.8**0.2) 13.3%, CMC-Na (No. 1190 of the CMC die cell by Daicel Chemical Industries, Ltd.) was added 15.3%, silica (AIRO gell No. 300 of Japanese AERO Gell) was added for gelatin (foodstuffs grade of Nitta Gelatin, Inc.) 3.1% 20.4%, and application-of-pressure mixing was carried out until it became still more uniform. While the mixture was warm, it took out from the container of the pressurized kneader, and it spread to the 1.5-mm-thick sheet shaped with 2 rolls, the 50-micrometer-thick urethane film was pasted together to the one side, and it was considered as the sample. About Examples 2-6 and the comparative examples 1-6, the kind and grade of pectin were changed and it created similarly.

[0026]

[Table 6]

		成 分			ポリイソブチレン	ブチルゴム	ベクチン	カカルのボナキシリウム塩セルロ	ゼラチン	シリカ
試 料		ベクチン			種類	グレード	含有量			
実 施 例	1	リゴン	H M	適量	43.4	2.6	15.3	15.3	20.4	3.1
	2			不足	43.4	2.6	3	27.6	20.4	3.1
	3			過剰	35	0	65	0	0	0
	4	リゴン	L M	適量	40.8	5.1	12.8	12.8	25.5	3.1
	5			不足	40.8	5.1	3	22.6	25.5	3.1
	6			過剰	35	0	65	0	0	0
比 較 例	1	柑橘類	H M	適量	43.4	2.6	15.3	15.3	20.4	3.1
	2			不足	43.4	2.6	3	27.6	20.4	3.1
	3			過剰	35	0	65	0	0	0
	4	柑橘類	L M	適量	40.8	5.1	12.8	12.8	25.5	3.1
	5			不足	40.8	5.1	3	22.1	25.5	3.1
	6			過剰	35	0	65	0	0	0

単位%

[0027]The result of having carried out measurement evaluation of the various physical properties when using it for a human body about Examples 1-6 and the comparative examples 1-6 is shown in Table 7.

[0028]

[Table 7]

評価物性 試料	制菌作用 の有無	緩衝作用 の有無	pH値	吸水性 (%)	その他、粘着性、保形性、柔軟性等
実施例	1	◎	○	4.5	550 粘着性、保形性、柔軟性耐久性とも良好であった。
	2	○	◎	5.5	650 同上
	3	◎	○	3.0	300 粘着性弱い 少し柔軟性に欠ける
	4	◎	○	4.5	550 粘着性、保形性、柔軟性耐久性とも良好であった。
	5	○	◎	5.5	650 同上
	6	◎	○	3.0	350 粘着性弱い 少し柔軟性に欠ける
比較例	1	△	△	5.0	600 粘着性、保形性、柔軟性耐久性とも良好であった。
	2	×	○	6.0	700 同上
	3	○	△	4.0	400 硬い
	4	△	○	5.5	580 粘着性、保形性、柔軟性耐久性とも良好であった。
	5	×	△	6.0	700 同上
	6	○	△	4.5	400 硬い

[0029]In Table 7, the check of fungistatic action used the *Staphylococcus aureus*, the *streptococci*, *Pseudomonas aeruginosa*, *Escherichia coli*, and the *Candida bacillus* which were used in Tables 1-5. SCDLP was used for the culture medium for bacteria, with pour plate

method, it cultivated for 24 hours and evaluated by 37 **, and the culturing method used GPLP for the culture medium at the fungus, and with pour plate method, it was cultivated for three days and it evaluated it by 26 **. The result shown in the result tables 1-5 and the result of the tendency were obtained. O It is shown that a seal has fungistatic action dramatically and that O seal does not have a certain thing and ** seal, and some do not have a certain thing and x seal considerably. About pectin content, at 3%, the amounts of pectin separated from a compound run short, sufficient fungistatic action is not shown, and 60% and when superfluous, although the sterilization effect is demonstrated enough, when using it for a human body, it runs short of other physical properties, for example, absorptivity, adhesiveness, firmness, and pliability, and is not conversely preferred.

[0030]The buffer action dissolved the sample with purified water, and made the solution 1%, 0.1N of HCl was used as acid, and 0.1N of NaOH was used for it as alkali, and it investigated change of pH. Compared with the thing containing citruses origin pectin, it turned out that the buffer action of what contains apple origin pectin as a result is good.

[0031]pH dissolved the sample in purified water, created the solution 1%, and measured it with the pH electrode. After absorptivity dipped the sample at ordinary temperature into a lot of physiological salines for 24 hours, it was pulled up, and the moisture content to the weight of the original sample was calculated as %. The shape change at the time of a finger touch test and a water absorption test and acupressure feeling estimated adhesiveness, firmness, and hardness. As for those results, a big difference was not seen in particular from both pectin. However, in the finish color, apple origin pectin was ochre from citruses origin pectin to being blackish brown.

[0032]

[Effect of the Invention]Especially in this invention, apple origin pectin is used as one ingredient of a skin protective layer constituent.

therefore -- differing from the citruses origin pectin used conventionally -- bacteria (*Staphylococcus aureus*) it acts effective in streptococci, *Pseudomonas aeruginosa*, *Escherichia coli*, and a fungus (*Candida bacillus*), and the sterilization effect is shown, even if it moreover performs radappertization required as wound products, the sterilization effect does not change, but whether it has stuck on the skin for a long period of time or is adapted for the place where So festers easily, the obstacle by a bacillus can be prevented.

Since it has a pressure-sensitive binder ingredient and a hydrophilic component, it can adhere to the skin good, and the leaching solution from the perspiration and ** from the skin can be absorbed, the adhesion to the skin and a wound surface can be improved, permeation of the bacillus from the outside can be prevented, the stimulus to a wound surface can be eased, and it can be used comfortable. Since the hydrophilic component is furthermore contained, it can exfoliate without giving a damage to the new epidermis produced in the recovery process of **.

The skin protective layer constituent by this invention can be applied to various medical supplies attached to the medical-application tapes fixed to the skin for a long period of time, and the place which is easy to be polluted, and can acquire a remarkable medical effect.

[Translation done.]